

## Hungary: Orthopedic and Rehabilitation Equipment

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Rehabilitation, orthopedic and therapeutic products make up a large group of medical equipment and supplies. This report describes the market catering to those who have developed infirmities, who were born with disabilities, or have been injured and require the temporary or constant use of rehabilitation products. Rehabilitation products and equipment include everything from wheelchairs and walking aids to therapeutic equipment and massage equipment. Also products like back and knee supports, compression hosiery, bandages and prosthetics belong to this sub-sector. Similar rules and regulations apply to many personal, hygienic and/or daily living, homecare products like special bras, after mastectomy, syringes, self-testing for blood, incontinence related products or mobile toilets. In Hungary hearing aids, contact lenses, home oxygen units, etc. also belong to this group of products.

The Hungarian rehab products, manufactured locally, are less sophisticated than products available in Western countries. With patients' co-payment, many people prefer to purchase better quality, more sophisticated products.

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## SUMMARY

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### 1. A. MARKET HIGHLIGHTS

Hungary has an aging population. More than 20 percent of the population is over 60 years of age and the population (10 million in 2003) has been decreasing for the last fifteen years. Life expectancy is 67 years for males and 75 years for females. The primary causes of increased morbidity and mortality are: cardiovascular diseases, cancers and chronic respiratory diseases.

Hungary spends \$600-650 per capita annually on health care compared to almost \$4,000 in the United States. In terms of GDP, this translates to 5-6 percent for Hungary (about one-third of the Organization for Economic Cooperation and Development's average).

Following the pattern of West European industrialized countries, Hungary has opted to retain a predominantly public funded health system with an increasing degree of services provided by private companies and increasing co-payment by the patients.

The Hungarian health care system provides general services to all Hungarian nationals and guarantees free access to all necessary medical care, except for such "non-essential" services as cosmetic surgery and private hospital rooms. The system also provides for the partial or sometimes complete reimbursement of rehab products required by the patient. The market for rehabilitation equipment and supply makes up an increasing share of overall healthcare expenditures. Although rehab products make up only about 3% of the NHIF's total expenditures, when adding patients' co-payment along with consumers' over-the-counter purchases, the share within total expenditures is much higher. Due to a lack of statistics it is not known in what percentage the rehab market is covered by the NHIF and how much is contributed by the patients. However NHIF data show that since 2000, every year, NHIF increased the amount spent on rehab products by over 10%. According to the Fund's officials they spent \$150 Million on rehab products in 2003 and have a budget of \$170 Million for 2004.

As mentioned earlier, health insurance in Hungary is currently provided only by the NHIF. While the concept of supplemental health insurance has been accepted as a matter of policy, the structure for such insurance programs has yet to be worked out. Currently some early forms of independent private health insurance coverage are being developed although they are designed more for companies than for private individuals.

## 2. COMPETITIVE ANALYSIS

The Hungarian medical market is very competitive. Regarding low-tech products local production is important. The ready-made, higher quality rehab product market (incl. sport health products) is dominated by imports. It is estimated that about 80% of the over \$250 million is spent on foreign products; the rest goes for locally produced equipment and supplies. The import of all medical products is fully liberalized.

Patient's private co-payment is significant and is on the rise on rehab products. Therefore, when purchasing medical goods and products, customers look for established companies with traditional, reliable after-sales service.

### 2. A. Domestic Production

Hungarian companies supply local products for less than 20% of the rehab market, in value. In volume it represents a higher share, as Hungarian products are generally cheaper and rather low-tech. There are a great number of small companies in Hungary engaged in the production of various types of rather low-tech rehab products, like daily living equipment, mobility equipment incl. wheelchairs, bandages, syringes, ankle and knee supports, anti-decubitus products etc. Others specialize in customs-made products like corsets, orthopedic footwear, prosthetics, etc. Local manufacturers, in addition to their manufacturing activity, often take up distribution of certain foreign products that fit into their product range. All local production originates from private companies, as there are no remaining state-owned companies in the medical field.

### 2. B. Third-Country Imports

American companies face stiff competition from West European companies in Hungary. German, Austrian, Italian and British firms have been present for many years in the market. Germany has been the sales leader for decades with an import market share of over 20% in the overall medical and rehab market.

The proximity of the European firms to the Hungarian market allows them frequent visits to meet the end-users, to participate in exhibitions and scientific meetings, and to provide prompt after-sales services to buyers. A partial list of European medical companies present in the Hungarian market include: Scholl, Meyra, Amoena, Coloplast, Otto Bock, SCA Hygiene, Dietz, Russka, bioCare

Some of them have established manufacturing units in Hungary for serving their Central-Eastern European market.

## 2. C. U.S. Market Position

U.S. products account for approximately 10-15 percent of total medical product imports to Hungary, their share in the rehab market is estimated to be lower. On the other hand, in addition to the "official statistics," a number of European subsidiaries of American companies are shipping products to Hungary registered as goods from Germany and the U.K (among others).

The Hungarian market is very receptive to U.S. medical equipment due to its high quality. A permanent presence through a local firm that can contact end-users and demonstrate product samples is indispensable for successfully marketing medical goods. The U.S. Commercial Service's matchmaking services (Gold Key service, International Partner Search, Customized market Research) are proven, cost effective programs that link U.S. companies to potential Hungarian partners and provide follow up assistance. Cooperating with the local distributor, participating at various scientific seminars, conferences and advertising in local medical papers are also important tools for market penetration in Hungary.

A few American companies have their own representative/sales offices in Hungary, while most distribute their products through local firms which act as distributors for them.

U.S. companies present in the market include: Bard Medical, Convatec, 3M, Johnson & Johnson, Smith & Nephew, Starkey Laboratory, Tyco Healthcare.

## 3. END-USERS – Insurance' co-payment

The actual users, end-users of the rehab products are the patients. Hospitals, certain departments have only some "real", special rehab products available for their patients' use while hospitalized. However, out and in-patient care institutions use a lot of products of this huge product group, like various bandages etc. All of this is part of the financing system with the NHIF.

For personal use at home patients have to get their own crutches, decubitus products, etc. They can either buy them in the shops for full price, or have them prescribed by the doctor entitled to do so. The National Health Insurance Fund (NHIF) decides which doctor is eligible to prescribe what product with NHIF contribution.

Every year the NHIF in coordination with the Ministry of Health and the Ministry of Finance allocate a certain part (around 3%) of the total health care budget for rehabilitation products. It is also the responsibility of NHIF to decide, based on cooperation with various committees, which products are eligible for co-payments and the percentages. The list of subsidized products is very long. According to NHIF officials, the Hungarian list is more extensive than the German or Swedish one. NHIF subsidy to rehab product is set either as a percentage of the reference-priced product or a fixed amount, based on the Committee's decision. Eventually the contribution has little relation to the actual price, as the basis is the reference price, often the lowest price offered in the given product group. In the case of the fix-amount contribution, the situation is similar. The co-payment is a fixed amount regardless of the actual price of the product.

When a patient needs a rehab product, the family or specialized doctor decides whether he/she is eligible for a financial contribution, based on the patient's status and the actual regulations. With the doctor's prescription, the patient pays only a part of the price (depending on the NHIF's current listing 50, 70, 85,95 or 100%) in the shop. The retailer will be reimbursed by the NHIF for the outstanding amount retroactively, when submitting the prescription to NHIF. Due to this system, cheaper products are more in demand in the prescription system. Higher quality, more sophisticated products are purchased by better-off patients over-the-counter, often for full price even if some contribution would be available.

#### 4. MARKET ACCESS

##### 4. A. Import climate

The import of all medical products is fully liberalized. U.S. exports to Hungary are based on most-favored-nation (MFN) status. From May 2004, when Hungary joins the EU, the country will be part of the EU's External Tariff System, and will apply the same import duties as other EU countries do. Regarding the VAT system, no change is expected. All products, regardless of origin are subject to a 25% Value Added Tax (VAT), which is borne by the final customer (hospital or patient).

##### 4. B. Regulations – CE Marking

Hungary will become an EU member on May 1, 2004, and most current EU regulations will apply, like the CE marking based on EU Medical Devices Directives. All medical rehabilitation products marketed in Hungary must bear a CE mark. The requirements for CE marking vary from product to product depending on the associated risk. For products with low-risk (risk level I), the manufacturer may self-certify in compliance with EU requirements and affix the CE mark. For others the certification process of a notified body is required. Once a product has a CE marking by an eligible notified body, no further testing will be required for U.S. medical products when entering the Hungarian market. Market regulations include also EU and Hungarian standards that are basically identical.

##### 4. C. Distribution/Business Practices

Under Hungarian regulations, manufacturers must have an authorized representative/distributor in Hungary. This representative is "responsible" for the foreign product in the country. He handles the necessary registration process, provides necessary documentation incl. directions for use and labeling in Hungarian.

Major foreign companies have their own offices while others operate through local distributors. Most distributors handle several brands of the same type of equipment and/or several lines of medical equipment. There are small firms, however, who represent only one or two foreign companies.

Pricing is a key factor in selling rehabilitation products in Hungary, as the market is very price sensitive. Hospitals and other health care providers usually buy equipment directly from distributors. Institutions have more or less a free hand within their budget concerning what and where to buy, as long as they follow applicable public procurement rules.

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